



Applicant:

KIM et al.

NO. 10/735,519

Examiner:

Holmes, Rex R.

Serial No.:

10/735,519

December 12, 2003

Group Art Unit:

3762

Filed:

Docket No.:

GUID.160PA

Title:

CARDIAC RESPONSE CLASSIFICATION USING MULTISITE SENSING AND PACING

CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence and the papers, as described herein, are being deposited in the United States Postal Service, as first class mail, in an envelope addressed to: Board of Patent Appeals and Interferences, United States Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450, on September 15, 2008.

Tracey M. Dotter

#### APPEAL BRIEF

Board of Patent Appeals and Interferences United States Patent and Trademark Office P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

This Appeal Brief is submitted pursuant to 37 C.F.R. § 41.37 for the above-referenced patent application, consistent with the Notice of Appeal filed May 6, 2008, with a Certificate of Mailing dated April 29, 2008. Appellant also submitted a Pre-Appeal Brief Request, to which the USPTO issued an adverse Panel Decision on June 13, 2008. A Petition for a 2-month Extension of Time pursuant to 37 C.F.R. § 1.136(a) is being submitted herewith to extend the deadline for reply to September 15, 2008 (September 13 is a Saturday). This Appeal Brief is therefore believed to be timely filed.

If necessary, please charge Deposit Account No. 50-3581 (GUID.160PA) in the amount of \$510.00 for this brief in support of appeal as indicated in 37 C.F.R. § 41.20(b)(2). If necessary, authority is given to charge/credit deposit account 50-3581 (GUID.160PA) any additional fees/overages in support of this filing.

09/18/2008 SSANDARA 00000023 503581

10735519

02 FC:1402

510.00 DA

# TABLE OF CONTENTS

| I.    | Real Party in Interest                        |  |     |
|-------|---|--|-----|
| II.   | RELATED APPEALS AND INTERFERENCES2            |  | . 2 |
| III.  | STATUS OF CLAIMS                              |  |     |
| IV.   | STATUS OF AMENDMENTS                          |  |     |
| V.    | SUMM  | SUMMARY OF CLAIMED SUBJECT MATTER  |     |
| VI.   | GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL |  |     |
|       | A.  | Claims 1-23, 35-48, 50-60, 62, and 63 stand rejected under 35 U.S.C. §112, fi paragraph, as failing to comply with the written description requirement                                 |     |
|       | B.  | Claims 38, 41, and 56 stand provisionally rejected on the ground of nonstatute obviousness-type double patenting in view of claim 11 of U.S. Application Serial No. 10/734,599.        | -   |
|       | C.  | Claims 38, 41, and 56 stand provisionally rejected on the ground of nonstatute obviousness-type double patenting in view of claims 1-94 of U.S. Application Serial No. 10/733,869      | า   |
| VII.  | ARGUMENT                                      |  |     |
|       | A.  | The rejection under 35 U.S.C. §112, first paragraph, of claims 1-23, 35-48, 50 60, 62, and 63 is improper because the written description requirement is satisfied.                    |     |
|       |   | Claims 1-23, 39-48, 50, 51, 57-60, and 63  | 16  |
|       |   | Claims 35-38, 52-56, and 62  | 20  |
|       | B.  | The obviousness-type double patenting rejection of claims 38, 41, and 56 ove the 10/734,599 application is moot because a terminal disclaimer over the '59 application has been filed. | 9   |
|       | C.  | The obviousness-type double patenting rejection of claims 38, 41, and 56 ove the 10/733,869 application is moot because a terminal disclaimer over the '86 application has been filed  | 59  |
| VIII. | Conc  | ONCLUSION  |     |
| IX.   | CLAIMS APPENDIX                               |  |     |
| X.    | EVIDENCE APPENDIX                             |  |     |
| XI.   | RELATED PROCEEDINGS APPENDIX                  |  |     |

# I. REAL PARTY IN INTEREST

The real party in interest is the assignee, Cardiac Pacemakers, Inc.

# II. RELATED APPEALS AND INTERFERENCES

Appellant is unaware of any related appeals, interferences, or judicial proceedings that would have a bearing on the Board's decision in the instant appeal.

# III. STATUS OF CLAIMS

Claims 1-23, 35-48, 50-60, 62, and 63 are currently pending in the application. Each of these claims has been finally rejected by the Examiner's action dated January 30, 2008 (hereinafter "Final Office Action"), from which Appellant appeals. All pending claims are therefore being appealed, and are listed in the Claims Appendix.

# IV. STATUS OF AMENDMENTS

A Response under 37 C.F.R. § 1.116 was filed after the Final Office Action, but it included no amendments. A subsequent Advisory Action indicated the response was considered but did not place the application in condition for allowance.

#### V. SUMMARY OF CLAIMED SUBJECT MATTER

The invention as presently claimed relates generally to implantable medical devices and to classifying a cardiac response following delivery of a pace pulse based on multisite sensing and pacing. (See, e.g., page 1, lines 9-11.)

Independent claim 1 is directed to a method of determining a cardiac response to a pacing pulse. (See, e.g., page 11, line 19 to page 12, line 2; page 29, line 11 to page 31, line 6; page 39, line 19 to page 42, line 8; page 42, line 19 to page 43, line 27; page 46, line 9 to page 47, line 25; page 54, line 10 to page 56, line 2; reference numerals 610, 620, 630, 640 (FIG. 6C), 650, 655, 660, 665 (FIG. 6A), 670, 675, 680, 685 (FIG. 6B), 810-832 (FIG. 8A), 840-866 (FIG. 8B), 1010, 1020, 1030, 1040 (FIG. 10), 1210-1265 (FIG. 12), 1505-1580 (FIG. 15), and 1810-1865 (FIG. 18).) The method includes providing a plurality of electrodes electrically coupled to a heart. (See, e.g., page 11, lines 11-18; page 14, line 1 to page 16, line 27; page 27, lines 20-28; page 29, lines 11-14 and 24-28; reference numerals 111, 112, 113, 114, 115, 116, 117, 118, 154, 156, 208, 209, 266, 267, 271, 272, 650, and 670.) The method also includes delivering the pacing pulse to the heart using a first electrode combination. (See, e.g., page 4, line 8 to page 5, line 24; page 11, lines 11-18; page 15, line 1 to page 16, line 27; page 23, lines 3-26; page 25, line 14 to page 26, line 12; page 27, lines 20-22; page 29, lines 1-10 and 17-23; reference numerals 111, 112, 113, 115, 117, 118, 154, 156, 209, 266, 267, 655, 675, 710, 715, 760, 768, 769, 770, 814, 844, 1110, 1215, 1301, 1505, 1610, 1710, and 1810.) The method also includes sensing a single cardiac signal for cardiac response classification following the pacing pulse using a second electrode combination. (See, e.g., page 4, line 8 to page 5, line 24; page 11, lines 11-18; page 15, line 1 to page 16, line 27; page 19, lines 1-26; page 20, lines 9-28; page 23, lines 3-26; page 24, lines 9-25; page 25, line 1 to page 26, line 12; page 29, lines 1-10 and 17-23; reference numerals 112, 113, 114, 116, 117, 154, 156, 208, 209, 231, 232, 235, 236, 237, 620, 660, 680, 765, 771, 818, 848, 1020, 1225, and 1630.) The foregoing elements of the method are neatly summarized in the first three boxes 650, 655, and 660 of FIG. 6A:

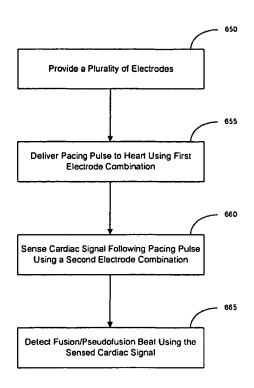


Figure 6A

The method of claim 1 further includes classifying the cardiac response to the pacing pulse as one of a captured response, a non-captured response, and a fusion/pseudofusion beat (*see*, *e.g.*, page 4, line 3 to page 5, line 24; page 11, line 19 to page 12, line 2; page 22, lines 7-24; page 23, lines 13-21; page 29, line 11 to page 31, line 6; page 39, line 19 to page 40, line 11; page 40, line 24 to page 41, line 17; page 42, lines 3-8; page 42, line 19 to page 43, line 27; page 46, line 9 to page 47, line 19; page 54, line 10 to page 55, line 23; reference numerals 640, 665, 685, 826, 830, 832, 860, 864, 866, 1040, 1235, 1245, 1255, 1515, 1525, 1565, 1820, 1840, 1860), and doing so using only the single cardiac signal (*see*, *e.g.*, page 8, lines 14-22; page 9, lines 1-3, 8-9, and 15-16; page 39, line 19 to page 41, line 17; page 42, line 19 to page 43, line 27; page 46, line 9 to page 47, line 25; page 54, line 10 to page 55, line 23; reference numerals 810-832 (FIG. 8A), 840-866 (FIG. 8B), 1210-1265 (FIG. 12), 1505-1580 (FIG. 15), and 1810-1865 (FIG. 18)).

Independent claim **15** is also directed to a method of determining a cardiac response to a pacing pulse. (*See*, *e.g.*, page 11, line 19 to page 12, line 2; page 29, line 11 to page 31, line 6; page 39, line 19 to page 42, line 8; page 42, line 19 to page 43, line 27; page 46, line 9 to page 47, line 25; page 54, line 10 to page 56, line 2; reference numerals 610, 620, 630, 640

(FIG. 6C), 650, 655, 660, 665 (FIG. 6A), 670, 675, 680, 685 (FIG. 6B), 810-832 (FIG. 8A), 840-866 (FIG. 8B), 1010, 1020, 1030, 1040 (FIG. 10), 1210-1265 (FIG. 12), 1505-1580 (FIG. 15), and 1810-1865 (FIG. 18).) Like claim 1, the method includes providing a plurality of electrodes electrically coupled to a heart. (See, e.g., page 11, lines 11-18; page 14, line 1 – page 16, line 27; page 27, lines 20-28; page 29, lines 11-14 and 24-28; reference numerals 111, 112, 113, 114, 115, 116, 117, 118, 154, 156, 208, 209, 266, 267, 271, 272, 650, and 670.) The method also includes delivering the pacing pulse to the heart using a first electrode combination. (See, e.g., page 4, line 8 to page 5, line 24; page 11, lines 11-18; page 15, line 1 to page 16, line 27; page 23, lines 3-26; page 25, line 14 to page 26, line 12; page 27, lines 20-22; page 29, lines 1-10 and 17-23; reference numerals 111, 112, 113, 115, 117, 118, 154, 156, 209, 266, 267, 655, 675, 710, 715, 760, 768, 769, 770, 814, 844, 1110, 1215, 1301, 1505, 1610, 1710, and 1810.) The method also includes sensing a single cardiac signal for cardiac response classification following the pacing pulse using a second electrode combination. (See, e.g., page 4, line 8 to page 5, line 24; page 11, lines 11-18; page 15, line 1 to page 16, line 27; page 19, lines 1-26; page 20, lines 9-28; page 23, lines 3-26; page 24, lines 9-25; page 25, line 1 to page 26, line 12; page 29, lines 1-10 and 17-23; reference numerals 112, 113, 114, 116, 117, 154, 156, 208, 209, 231, 232, 235, 236, 237, 620, 660, 680, 765, 771, 818, 848, 1020, 1225, and 1630.) Finally, the method includes classifying the cardiac response to the pacing pulse as one of at least three cardiac response types (see, e.g., page 4, line 3 to page 5, line 24; page 11, line 19 to page 12, line 2; page 22, lines 7-24; page 23, lines 13-21; page 29, line 11 to page 31, line 6; page 39, line 19 to page 40, line 11; page 40, line 24 to page 41, line 17; page 42, lines 3-8; page 42, line 19 to page 43, line 27; page 46, line 9 to page 47, line 19; page 54, line 10 to page 55, line 23; reference numerals 640, 665, 685, 826, 830, 832, 860, 864, 866, 1040, 1235, 1245, 1255, 1515, 1525, 1565, 1820, 1840, 1860), and doing so using only the single cardiac signal (see, e.g., page 8, lines 14-22, page 9, lines 1-3, 8-9, and 15-16, page 39, line 19 to page 41, line 17, page 42, line 19 to page 43, line 27, page 46, line 9 to page 47, line 25, page 54, line 10 to page 55, line 23; reference numerals 810-832 (FIG. 8A), 840-866 (FIG. 8B), 1210-1265 (FIG. 12), 1505-1580 (FIG. 15), and 1810-1865 (FIG. 18)).

Independent claim 35 is directed to a method of detecting a fusion/pseudofusion beat. (See, e.g., page 11, line 19 to page 12, line 2; page 29, line 11 to page 31, line 6; page 39, line

19 to page 42, line 8; page 42, line 19 to page 43, line 27; page 46, line 9 to page 47, line 25; page 54, line 10 to page 56, line 2; reference numerals 610, 620, 630, 640 (FIG. 6C), 650, 655, 660, 665 (FIG. 6A), 670, 675, 680, 685 (FIG. 6B), 810-832 (FIG. 8A), 840-866 (FIG. 8B), 1010, 1020, 1030, 1040 (FIG. 10), 1210-1265 (FIG. 12), 1505-1580 (FIG. 15), and 1810-1865 (FIG. 18).) Like claims 1 and 15, the method includes providing a plurality of electrodes electrically coupled to a heart (see, e.g., page 11, lines 11-18; page 14, line 1 to page 16, line 27; page 27, lines 20-28; page 29, lines 11-14 and 24-28; reference numerals 111, 112, 113, 114, 115, 116, 117, 118, 154, 156, 208, 209, 266, 267, 271, 272, 650, and 670), delivering a pacing pulse to the heart using a first electrode combination (see, e.g., page 4, line 8 to page 5, line 24; page 11, lines 11-18; page 15, line 1 to page 16, line 27; page 23, lines 3-26; page 25, line 14 to page 26, line 12; page 27, lines 20-22; page 29, lines 1-10 and 17-23; reference numerals 111, 112, 113, 115, 117, 118, 154, 156, 209, 266, 267, 655, 675, 710, 715, 760, 768, 769, 770, 814, 844, 1110, 1215, 1301, 1505, 1610, 1710, and 1810), and sensing a single cardiac signal for cardiac response classification following the pacing pulse using a second electrode combination (see, e.g., page 4, line 8 to page 5, line 24; page 11, lines 11-18; page 15, line 1 to page 16, line 27; page 19, lines 1-26; page 20, lines 9-28; page 23, lines 3-26; page 24, lines 9-25; page 25, line 1 to page 26, line 12; page 29, lines 1-10 and 17-23; reference numerals 112, 113, 114, 116, 117, 154, 156, 208, 209, 231, 232, 235, 236, 237, 620, 660, 680, 765, 771, 818, 848, 1020, 1225, and 1630). The method also includes detecting the fusion/pseudofusion beat using only the single cardiac signal (see, e.g., page 4, line 3 to page 5, line 24; page 7, lines 21-22; page 8, lines 14-22; page 9, lines 1-3, 8-9, and 15-16; page 11, line 19 to page 12, line 2; page 17, line 22 to page 18, line 12; page 22, lines 7-24; page 23, lines 13-21; page 29, line 11 to page 31, line 6; page 39, line 19 to page 40, line 11; page 40, line 24 to page 41, line 17; page 42, lines 3-8; page 42, line 19 to page 43, line 27; page 46, line 9 to page 47, line 19; page 54, line 10 to page 55, line 23; reference numerals 220, 225, 283, 640, 650-665 (FIG. 6A), 685, 810-832 (FIG. 8A), 840-866 (FIG. 8B), 1040, 1210-1265 (FIG. 12), 1505-1580 (FIG. 15), and 1810-1865 (FIG. 18)).

Independent claim **39** is directed to a medical device that includes a plurality of electrodes electrically coupled to a heart. (*See, e.g.,* page 11, lines 11-18; page 14, line 1 to page 16, line 27; page 27, lines 20-28; page 29, lines 11-14 and 24-28; reference numerals 111, 112, 113, 114, 115, 116, 117, 118, 154, 156, 208, 209, 266, 267, 271, 272, 650, and

670.) The device also includes a pulse delivery circuit configured to deliver a pacing pulse to a heart using a first electrode combination. (See, e.g., page 4, line 8 to page 5, line 24; page 11, lines 11-18; page 15, line 1 to page 16, line 27; page 22, line 25 to page 23, line 26; page 23, lines 3-26; page 25, line 14 to page 26, line 12; page 27, lines 20-22; page 29, lines 1-10 and 17-23; reference numerals 111, 112, 113, 115, 117, 118, 154, 156, 209, 220, 222, 241, 242, 243, 244, 266, 267, 655, 675, 710, 715, 760, 768, 769, 770, 814, 844, 1110, 1215, 1301, 1505, 1610, 1710, and 1810.) The device also includes a sensing circuit configured to sense a single cardiac signal for cardiac response classification following the pacing pulse using a second electrode combination. (See, e.g., page 4, line 8 to page 5, line 24; page 11, lines 11-18; page 15, line 1 to page 16, line 27; page 19, lines 1-26; page 20, lines 9-28; page 23, lines 3-26; page 24, lines 9-25; page 25, line 1 to page 26, line 12; page 29, lines 1-10 and 17-23; reference numerals 112, 113, 114, 116, 117, 154, 156, 208, 209, 231, 232, 235, 236, 237, 620, 660, 680, 765, 771, 818, 848, 1020, 1225, and 1630.) Finally, the device includes a control circuit that is coupled to the sensing circuit and configured to classify a cardiac response to the pacing pulse as one of at least three cardiac response types using only the sensed cardiac signal (see, e.g., page 4, line 3 to page 5, line 24; page 8, lines 14-22; page 9, lines 1-3, 8-9, and 15-16; page 11, line 19 to page 12, line 2; page 22, lines 7-24; page 23, lines 13-21; page 29, line 11 to page 31, line 6; page 39, line 19 to page 40, line 11; page 40, line 24 to page 41, line 17; page 42, lines 3-8; page 42, line 19 to page 43, line 27; page 46, line 9 to page 47, line 19; page 54, line 10 to page 55, line 23; reference numerals 220, 283, 640, 665, 685, 810-832 (FIG. 8A), 840-866 (FIG. 8B), 1040, 1210-1265 (FIG. 12), 1505-1580 (FIG. 15), and 1810-1865 (FIG. 18)).

Independent claim **52** is also directed to a medical device that includes a plurality of electrodes electrically coupled to a heart (*see, e.g.*, page 11, lines 11-18; page 14, line 1 to page 16, line 27; page 27, lines 20-28; page 29, lines 11-14 and 24-28; reference numerals 111, 112, 113, 114, 115, 116, 117, 118, 154, 156, 208, 209, 266, 267, 271, 272, 650, and 670), a pulse delivery circuit configured to deliver a pacing pulse to a heart using a first electrode combination, (*see, e.g.*, page 4, line 8 to page 5, line 24; page 11, lines 11-18; page 15, line 1 to page 16, line 27; page 22, line 25 to page 23, line 26; page 23, lines 3-26; page 25, line 14 to page 26, line 12; page 27, lines 20-22; page 29, lines 1-10 and 17-23; reference numerals 111, 112, 113, 115, 117, 118, 154, 156, 209, 220, 222, 241, 242, 243, 244, 266,

267, 655, 675, 710, 715, 760, 768, 769, 770, 814, 844, 1110, 1215, 1301, 1505, 1610, 1710, and 1810), and a sensing circuit configured to sense a single cardiac signal for cardiac response classification following the pacing pulse using a second electrode combination (see, e.g., page 4, line 8 to page 5, line 24; page 11, lines 11-18; page 15, line 1 to page 16, line 27; page 19, lines 1-26; page 20, lines 9-28; page 23, lines 3-26; page 24, lines 9-25; page 25, line 1 to page 26, line 12; page 29, lines 1-10 and 17-23; reference numerals 112, 113, 114, 116, 117, 154, 156, 208, 209, 231, 232, 235, 236, 237, 620, 660, 680, 765, 771, 818, 848, 1020, 1225, and 1630). Finally, the device of claim 52 includes a control circuit that is coupled to the sensing circuit and configured to detect a fusion/pseudofusion beat using only the sensed cardiac signal. (See, e.g., page 4, line 3 to page 5, line 24; page 7, lines 21-22; page 8, lines 14-22; page 9, lines 1-3, 8-9, and 15-16; page 11, line 19 to page 12, line 2; page 17, line 22 to page 18, line 12; page 22, lines 7-24; page 23, lines 13-21; page 29, line 11 to page 31, line 6; page 39, line 19 to page 40, line 11; page 40, line 24 to page 41, line 17; page 42, lines 3-8; page 42, line 19 to page 43, line 27; page 46, line 9 to page 47, line 19; page 54, line 10 to page 55, line 23; reference numerals 220, 225, 283, 640, 650-665 (FIG. 6A), 685, 810-832 (FIG. 8A), 840-866 (FIG. 8B), 1040, 1210-1265 (FIG. 12), 1505-1580 (FIG. 15), and 1810-1865 (FIG. 18).)

Independent claim **57** is directed to a medical device for classifying a cardiac response. (*See, e.g.*, page 7, lines 7-15 and 23-27; page 8, lines 14-27; page 9, lines 1-16; page 11, line 19 to page 12, line 2; page 17, line 1 to page 18, line 12; page 23, line 13 to page 24, line 8; page 26, line 27 to page 28, line 14; reference numerals 100-209 (FIG. 1), 111-290 (FIG. 2A), 261-269 (FIG. 2B), 271-285 (FIG. 2C).) The device includes means for providing a plurality of electrodes electrically coupled to a heart. (*See, e.g.*, page 11, lines 11-18; page 14, line 1 to page 16, line 27; page 27, lines 20-28; page 29, lines 11-14 and 24-28; reference numerals 111, 112, 113, 114, 115, 116, 117, 118, 154, 156, 208, 209, 266, 267, 271, 272, 650, and 670.) The device also includes means for delivering the pacing pulse to the heart using a first electrode combination. (*See, e.g.*, page 4, line 8 to page 5, line 24; page 11, lines 11-18; page 15, line 1 to page 16, line 27; page 22, line 25 to page 23, line 26; page 23, lines 3-26; page 25, line 14 to page 26, line 12; page 27, lines 20-22; page 29, lines 1-10 and 17-23; reference numerals 111, 112, 113, 115, 117, 118, 154, 156, 209, 220, 222, 241, 242, 243, 244, 266, 267, 655, 675, 710, 715, 760, 768, 769, 770, 814, 844, 1110, 1215, 1301,

1505, 1610, 1710, and 1810.) The device also includes means for sensing a single cardiac signal for cardiac response classification following the pacing pulse using a second electrode combination. (See, e.g., page 4, line 8 to page 5, line 24; page 11, lines 11-18; page 15, line 1 to page 16, line 27; page 19, lines 1-26; page 20, lines 9-28; page 23, lines 3-26; page 24, lines 9-25; page 25, line 1 to page 26, line 12; page 29, lines 1-10 and 17-23; reference numerals 112, 113, 114, 116, 117, 154, 156, 208, 209, 231, 232, 235, 236, 237, 620, 660, 680, 765, 771, 818, 848, 1020, 1225, and 1630.) Finally, the device of claim 57 includes means for classifying the cardiac response to the pacing pulse as one of a captured response, a non-captured response, and a fusion/pseudofusion beat using only the single cardiac signal. (See, e.g., page 4, line 3 to page 5, line 24; page 8, lines 14-22; page 9, lines 1-3, 8-9, and 15-16; page 11, line 19 to page 12, line 2; page 22, lines 7-24; page 23, lines 13-21; page 29, line 11 to page 31, line 6; page 39, line 19 to page 40, line 11; page 40, line 24 to page 41, line 17; page 42, lines 3-8; page 42, line 19 to page 43, line 27; page 46, line 9 to page 47, line 19; page 54, line 10 to page 55, line 23; reference numerals 220, 283, 640, 665, 685, 810-832 (FIG. 8A), 840-866 (FIG. 8B), 1040, 1210-1265 (FIG. 12), 1505-1580 (FIG. 15), and 1810-1865 (FIG. 18).)

Independent claim **59** is directed to a medical device for determining a cardiac response to a pacing pulse. (*See, e.g.*, page 7, lines 7-15 and 23-27; page 8, lines 14-27; page 9, lines 1-16; page 11, line 19 to page 12, line 2; page 17, line 1 to page 18, line 12; page 23, line 13 to page 24, line 8; page 26, line 27 to page 28, line 14; reference numerals 100-209 (FIG. 1), 111-290 (FIG. 2A), 261-269 (FIG. 2B), 271-285 (FIG. 2C).) The device includes means for providing a plurality of electrodes electrically coupled to a heart. (*See, e.g.*, page 11, lines 11-18; page 14, line 1 to page 16, line 27; page 27, lines 20-28; page 29, lines 11-14 and 24-28; reference numerals 111, 112, 113, 114, 115, 116, 117, 118, 154, 156, 208, 209, 266, 267, 271, 272, 650, and 670.) The device also includes means for delivering the pacing pulse to the heart using a first electrode combination. (*See, e.g.*, page 4, line 8 to page 5, line 24; page 11, lines 11-18; page 15, line 1 to page 16, line 27; page 22, line 25 to page 23, line 26; page 23, lines 3-26; page 25, line 14 to page 26, line 12; page 27, lines 20-22; page 29, lines 1-10 and 17-23; reference numerals 111, 112, 113, 115, 117, 118, 154, 156, 209, 220, 222, 241, 242, 243, 244, 266, 267, 655, 675, 710, 715, 760, 768, 769, 770, 814, 844, 1110, 1215, 1301, 1505, 1610, 1710, and 1810.) The device also includes means for sensing a

single cardiac signal for cardiac response classification following the pacing pulse using a second electrode combination. (*See, e.g.,* page 4, line 8 to page 5, line 24; page 11, lines 11-18; page 15, line 1 to page 16, line 27; page 19, lines 1-26; page 20, lines 9-28; page 23, lines 3-26; page 24, lines 9-25; page 25, line 1 to page 26, line 12; page 29, lines 1-10 and 17-23; reference numerals 112, 113, 114, 116, 117, 154, 156, 208, 209, 231, 232, 235, 236, 237, 620, 660, 680, 765, 771, 818, 848, 1020, 1225, and 1630.) Finally, the device of claim 59 includes means for classifying the cardiac response as one of at least three cardiac response types using only the single cardiac signal. (*See, e.g.,* page 4, line 3 to page 5, line 24; page 8, lines 14-22; page 9, lines 1-3, 8-9, and 15-16; page 11, line 19 to page 12, line 2; page 22, lines 7-24; page 23, lines 13-21; page 29, line 11 to page 31, line 6; page 39, line 19 to page 40, line 11; page 40, line 24 to page 41, line 17; page 42, lines 3-8; page 42, line 19 to page 43, line 27; page 46, line 9 to page 47, line 19; page 54, line 10 to page 55, line 23; reference numerals 220, 283, 640, 665, 685, 810-832 (FIG. 8A), 840-866 (FIG. 8B), 1040, 1210-1265 (FIG. 12), 1505-1580 (FIG. 15), and 1810-1865 (FIG. 18).)

Independent claim 62 is directed to a system for detecting a fusion/pseudofusion beat. (See, e.g., page 7, lines 7-15 and 23-27; page 8, lines 14-27; page 9, lines 1-16; page 11, line 19 to page 12, line 2; page 17, line 1 to page 18, line 12; page 23, line 13 to page 24, line 8; page 26, line 27 to page 28, line 14; reference numerals 100-209 (FIG. 1), 111-290 (FIG. 2A), 261-269 (FIG. 2B), 271-285 (FIG. 2C)) The device includes means for providing a plurality of electrodes electrically coupled to a heart. (See, e.g., page 11, lines 11-18; page 14, line 1 to page 16, line 27; page 27, lines 20-28; page 29, lines 11-14 and 24-28; reference numerals 111, 112, 113, 114, 115, 116, 117, 118, 154, 156, 208, 209, 266, 267, 271, 272, 650, and 670.) The device also includes means for delivering the pacing pulse to the heart using a first electrode combination. (See, e.g., page 4, line 8 to page 5, line 24; page 11, lines 11-18; page 15, line 1 to page 16, line 27; page 22, line 25 to page 23, line 26; page 23, lines 3-26; page 25, line 14 to page 26, line 12; page 27, lines 20-22; page 29, lines 1-10 and 17-23; reference numerals 111, 112, 113, 115, 117, 118, 154, 156, 209, 220, 222, 241, 242, 243, 244, 266, 267, 655, 675, 710, 715, 760, 768, 769, 770, 814, 844, 1110, 1215, 1301, 1505, 1610, 1710, and 1810.) The device also includes means for sensing a single cardiac signal for cardiac pacing response classification following the pacing pulse using a second electrode combination. (See, e.g., page 4, line 8 to page 5, line 24; page 11, lines 11-18; page 15, line

1 to page 16, line 27; page 19, lines 1-26; page 20, lines 9-28; page 23, lines 3-26; page 24, lines 9-25; page 25, line 1 to page 26, line 12; page 29, lines 1-10 and 17-23; reference numerals 112, 113, 114, 116, 117, 154, 156, 208, 209, 231, 232, 235, 236, 237, 620, 660, 680, 765, 771, 818, 848, 1020, 1225, and 1630.) Finally, the device of claim 62 includes means for detecting the fusion/pseudofusion beat using only the single cardiac signal. (*See, e.g.*, page 4, line 3 to page 5, line 24; page 7, lines 21-22; page 8, lines 14-22; page 9, lines 1-3, 8-9, and 15-16; page 11, line 19 to page 12, line 2; page 17, line 22 to page 18, line 12; page 22, lines 7-24; page 23, lines 13-21; page 29, line 11 to page 31, line 6; page 39, line 19 to page 40, line 11; page 40, line 24 to page 41, line 17; page 42, lines 3-8; page 42, line 19 to page 43, line 27; page 46, line 9 to page 47, line 19; page 54, line 10 to page 55, line 23; reference numerals 220, 225, 283, 640, 650-665 (FIG. 6A), 685, 810-832 (FIG. 8A), 840-866 (FIG. 8B), 1040, 1210-1265 (FIG. 12), 1505-1580 (FIG. 15), and 1810-1865 (FIG. 18).)

The reader is reminded that a single structure may correspond to multiple "means" limitations. See, e.g., Winbond Electronics Corp. v. International Trade Commission, 4

Fed.Appx. 832, 839-40 (Fed. Cir. 2001). Also, structure and disclosure cited in one claim element may be relevant and/or employed in a subsequent claim element, including dependent claims. Furthermore, the structure corresponding to a "means" limitation may include a computer or microprocessor programmed to carry out a particular algorithm. See WMS Gaming, Inc. v. International Game Technology, 184 F.3d 1339, 1348, 51 USPQ2d 1385, \_\_\_\_ (Fed. Cir. 1999). Such an algorithm may be expressed in any understandable terms including as a mathematical formula, in prose, or as a flow chart, or in another suitable manner. See Finisar Corp. v. DirecTV Group, Inc., 523 F.3d 1323, 1340 (Fed. Cir. 2008).

As required by 37 C.F.R. § 41.37(c)(1)(v), a concise explanation of the subject matter defined in each of the independent claims involved in the appeal is provided herein. Appellant has identified representative subject matter for each of these claims; however, the abundance of supporting subject matter in the application prohibits identifying all textual and diagrammatic references to each claimed recitation. Thus, other application subject matter that supports the claims but is not specifically identified above may be found elsewhere in the application. This summary does not provide an exhaustive or exclusive view of the present subject matter, and Appellant refers to the appended claims and their legal equivalents for a complete statement of the invention.

## VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

- A. Claims 1-23, 35-48, 50-60, 62, and 63 stand rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement.
- B. Claims 38, 41, and 56 stand provisionally rejected on the ground of nonstatutory obviousness-type double patenting in view of claim 11 of U.S. Application Serial No. 10/734,599.
- C. Claims 38, 41, and 56 stand provisionally rejected on the ground of nonstatutory obviousness-type double patenting in view of claims 1-94 of U.S. Application Serial No. 10/733,869.

#### VII. ARGUMENT

Appellant maintains the traversal of each of the grounds of rejection.

In making a rejection under 35 U.S.C. § 112, first paragraph, the Examiner has the initial burden of presenting evidence or reasons why a person skilled in the art would not recognize in Appellant's disclosure a description of the invention defined by the claims. See *In re Wertheim*, 541 F.2d 257, 263, 191 USPQ 90, 97 (CCPA 1976). See also M.P.E.P. § 2163.04. The inquiry into whether the written description requirement is met must be determined on a case-by-case basis, and is a question of fact. See *In re Wertheim*, 541 F.2d at 262, 191 USPQ at 96; M.P.E.P. § 2163.04. Appellant respectfully submits that the requirements under 35 U.S.C. § 112, first paragraph, are fully satisfied by Appellant's original disclosure.

A. The rejection under 35 U.S.C. §112, first paragraph, of claims 1-23, 35-48, 50-60, 62, and 63 is improper because the written description requirement is satisfied.

In making the final rejection under 35 U.S.C. § 112, first paragraph, the Examiner contends that the language "using only the single cardiac signal" (and the like, i.e., "using only the sensed cardiac signal", hereinafter referred to as the "disputed language") in each of the independent claims 1, 15, 35, 39, 52, 59, and 62 is not disclosed in the original disclosure.

The written description requirement of 35 U.S.C. § 112, first paragraph is not rigid or wooden, but is flexible. Thus, to satisfy the written description requirement, word-for-word or *in haec verba* support for claimed subject matter is not required. See *Lockwood v. American Airlines*, 107 F.3d 1565, 1572 (Fed. Cir. 1997). Rather, the written description requirement merely stipulates that the disclosure "must convey with reasonable clarity to those skilled in the art that the inventor was in possession of the invention." *Crown Operations International v. Solutia Inc.*, 289 F.3d 1367, 1376 (Fed. Cir. 2002). The requirement is satisfied by the patentee's disclosure of such descriptive means as words, structures, figures, diagrams, formulas, etc., that fully set forth the claimed invention. See *Id.* Stated differently, one skilled in the art, reading the original disclosure, "must reasonably discern the limitation at issue in the claims." *Id.* With this as the standard for compliance with the first paragraph of §112, the as-filed application can be seen to clearly support the disputed language.

For purposes of claim grouping, we group the appealed claims according to the function associated with the disputed language. Independent claims 1, 15, 39, 57, and 59 associate the disputed language with some form of classifying a cardiac response as one of at least three cardiac response types. Method claim 1, for example, recites "classifying the cardiac response to the pacing pulse as one of a captured response, a non-captured response, and a fusion/pseudofusion beat using only the single cardiac signal". Device claim 59 recites "means for classifying the cardiac response as one of at least three cardiac response types using only the single cardiac signal". The remaining independent claims 35, 52, and 62 associate the disputed language with some form of detecting a fusion/pseudofusion beat. Claim 35, for example, is a method claim that recites "detecting the fusion/pseudofusion beat using only the single cardiac signal".

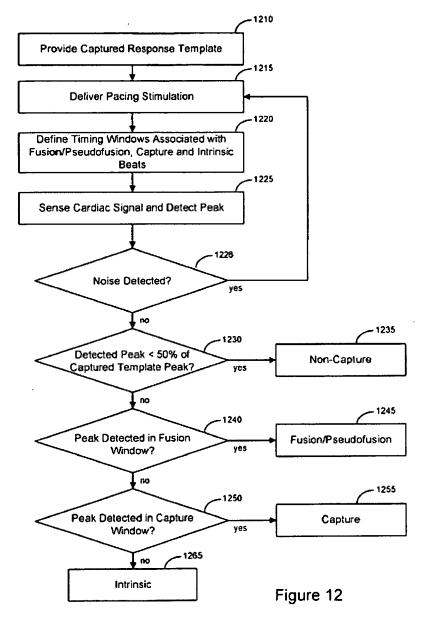
#### Claims 1-23, 39-48, 50, 51, 57-60, and 63

These claims associate the disputed language "using only the single cardiac signal" (or "using only the sensed cardiac signal") with some form of classifying a cardiac response as one of at least three cardiac response types. Claim 1, for example, recites "classifying the cardiac response to the pacing pulse as one of a captured response, a non-captured response, and a fusion/pseudofusion beat using only the single cardiac signal". Such a claim feature is plainly described in Appellant's original disclosure. Without using the term "only", the original disclosure describes the feature by explaining how characteristics of a particular cardiac signal are used--without recourse to other cardiac signals--to classify the cardiac response into one of three cardiac response types. Such an explanation is given, at least, in connection with several flowcharts.

Each such flowchart is described as illustrating a procedure for classifying a cardiac response. The original disclosure also provides a step-by-step description, showing how the classification is performed using characteristics of the particular cardiac signal, without recourse to other cardiac signals. The person skilled in the art reading this description would reasonably expect important aspects of the classification procedure to be shown or described. In particular, the skilled person would reasonably expect that if cardiac signals other than the particular cardiac signal are necessary to the classification procedure, they would be described. But no such other cardiac signals are in fact described. Therefore, the skilled

person reasonably concludes that the classification is carried out "using only the single cardiac signal", and the disclosure succeeds in "convey[ing] with reasonable clarity to those skilled in the art that the inventor[s] [were] in possession of the invention."

One flowchart and associated description that supplies the necessary written description of the objected-to claim feature is the flowchart of FIG. 12:



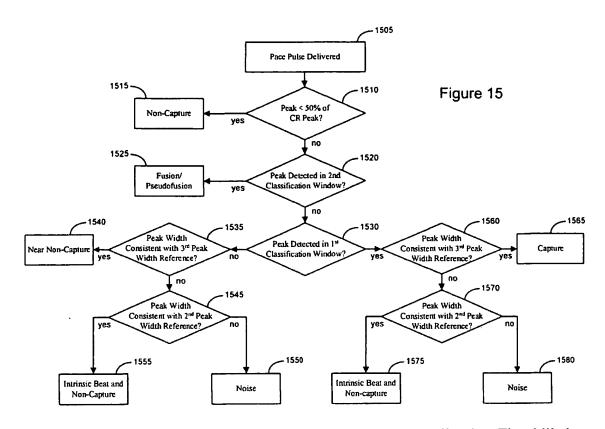
The skilled person reads at page 9 lines 1-3 that FIG. 12 "is a flowchart illustrating a method of classifying a cardiac response using fusion, capture, and intrinsic classification windows in accordance with an embodiment of the invention." The person then reads the detailed

description of the figure, from page 42, line 19 to page 43, line 27, in which the entire process from box 1210 through box 1265 is explained. The person discerns from the figure and the description that a pacing pulse is delivered to the heart at box 1215, and that a single cardiac signal is sensed at box 1225, and the peak *of that same signal* is detected. The person then discerns that, if no noise is detected, the cardiac response to the pacing pulse is classified as one of capture (box 1255), non-capture (box 1235), or fusion/pseudofusion (box 1245) by straightforward operation of the decision boxes 1250, 1230, and 1240 respectively. The person discerns from the decision boxes that these classifications are performed based on properties of the same cardiac signal, namely, the amplitude of the detected peak, and the detected peak's relative position with respect to the described classification windows.

Since the figure is described as "a flowchart illustrating a method of classifying a cardiac response ...", the person reasonably expects that important aspects of the method are shown or described. It would be unreasonable for the person to expect an important aspect of the classification method to be omitted. In particular, the person would consider it important to the method if a signal other than the particular cardiac signal described were used in the classification process. Hence, it would be unreasonable for the person to expect that a signal other than the particular cardiac signal described was used in the classification process. Put another way, the person reasonably discerns from FIG. 12 and its description that the classifying method uses the cardiac signal sensed at box 1225 and no other cardiac signal, i.e., that the classifying is performed "using only the single cardiac signal".

At least FIG. 12 and its description therefore succeeds in conveying with reasonable clarity to those skilled in the art that the inventors were in possession of the invention of claims 1-23, 39-48, 50, 51, 57-60, and 63. The original disclosure provides the necessary written description support under 35 U.S.C. § 112, first paragraph, for at least those claims. On this basis, the rejection of claims 1-23, 39-48, 50, 51, 57-60, and 63 under 35 U.S.C. § 112, first paragraph should be reversed.

FIG. 15 is another example of a flowchart the description of which provides written support for at least claims 1-23, 39-48, 50, 51, 57-60, and 63:



This flowchart is described chiefly from page 46, line 9 to page 47, line 25. The skilled person reads there that, after a pace pulse is delivered at box 1505, "a cardiac signal following the pacing stimulation is sensed", and "[t]he amplitude and width of the cardiac signal peak are determined". Thereafter, decision boxes 1510, 1520, 1530, and 1560 are described that compare these measured peak or width characteristics of the (single) cardiac signal -- but no characteristics of any other cardiac signal -- to certain classification windows or other reference values. On the basis of those comparisons involving only the characteristics of the single cardiac signal, the cardiac response is described as being classified as a non-captured response (box 1515), a fusion/pseudofusion response (box 1525), or a captured response (box 1565).

Just as with the description of FIG. 12, the skilled person reading the description of FIG. 15 reasonably expects that important aspects of the classification procedure are shown or described. In particular, the person would consider it important to the method if a signal other than the particular cardiac signal described were used in the classification process. No such other cardiac signal, however, is mentioned. Consequently, the skilled person reasonably discerns from FIG. 15 and its description that the classifying method uses the

cardiac signal sensed after box 1505 and before box 1510 and no other cardiac signal, i.e., that the classifying is performed "using only the single cardiac signal".

At least FIG. 15 and its description therefore succeeds in conveying with reasonable clarity to those skilled in the art that the inventors were in possession of the invention of claims 1-23, 39-48, 50, 51, 57-60, and 63. The original disclosure therefore provides the necessary written description support under 35 U.S.C. § 112, first paragraph, for at least those claims. On this basis, the rejection of claims 1-23, 39-48, 50, 51, 57-60, and 63 under 35 U.S.C. § 112, first paragraph should be reversed.

Besides the descriptions of FIGS. 12 and 15 discussed above, other written description can be readily identified in the original disclosure for the claim feature of classifying a cardiac response as one of a captured response, a non-captured response, and a fusion/pseudofusion beat (or as one of at least three cardiac response types) "using only the single cardiac signal", also without explicit use of the term "only". However, further examples are believed to be unnecessary in view of the foregoing explanations, and will not be further discussed.

#### Claims 35-38, 52-56, and 62

These claims associate the disputed language "using only the single cardiac signal" (or "using only the sensed cardiac signal") with some form of detecting a fusion/pseudofusion beat. Claim 35, for example, recites "detecting the fusion/pseudofusion beat using only the single cardiac signal". Such a claim feature is plainly described in Appellant's original disclosure. Without using the term "only", the original disclosure describes the feature by explaining how characteristics of a particular cardiac signal are used --without recourse to other cardiac signals-- in order to detect a fusion/pseudofusion beat, in response to a pacing pulse. Such an explanation is given, at least, in connection with several flowcharts.

FIGS. 12 and 15 are two such flowcharts. As demonstrated above, each of these flowcharts is described as illustrating a procedure for classifying a cardiac response. The original disclosure provides a step-by-step description, explaining how the classification is performed using characteristics of a particular cardiac signal sensed after a pacing pulse is delivered, without recourse to other cardiac signals. The person skilled in the art reading this

description reasonably expects that if cardiac signals other than the particular cardiac signal are necessary to the classification procedure, they would be described. But no such other cardiac signals are in fact described. Further, the flowcharts of FIGS. 12 and 15 each include the capability of classifying the cardiac signal as a fusion/pseudofusion beat (box 1245 in FIG. 12, box 1525 in FIG. 15), again without recourse to other cardiac signals. Since classifying the cardiac signal as a fusion/pseudofusion beat constitutes detecting a fusion/pseudofusion beat, the skilled person reasonably concludes from the original disclosure that the detection of the fusion/pseudofusion beat is carried out "using only the single cardiac signal", and the disclosure succeeds in conveying with reasonable clarity to those skilled in the art that the inventors were in possession of the invention.

The flowchart of FIG. 6A and its associated description confirms and reinforces the teachings of FIGS. 12 and 15 relating to detecting a fusion/pseudofusion beat using only the single cardiac signal, again without explicit use of the term "only". FIG. 6A is reproduced again below, and is described chiefly at page 29, lines 11-23:

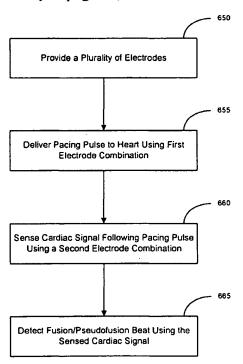


Figure 6A

After the pacing pulse is delivered to the heart (box 655), the (single) cardiac signal is sensed (box 660). A fusion/pseudofusion beat is then detected (box 665) "using the sensed cardiac

signal". Consistent with the more detailed diagrams of FIGS. 12 and 15, no other cardiac signals are mentioned as being used for the fusion/pseudofusion beat detection in the simpler flowchart of FIG. 6A. The skilled person would expect that if cardiac signals other than the particular one referred to were necessary to the detection, they would be mentioned. Since they are not, the skilled person again reasonably concludes that the detection of the fusion/pseudofusion beat is carried out "using only the single cardiac signal", and the disclosure succeeds in conveying with reasonable clarity to those skilled in the art that the inventors were in possession of the invention.

For the foregoing reasons, at least FIGS. 6A, 12, and 15 and their respective descriptions succeed in conveying with reasonable clarity to those skilled in the art that the inventors were in possession of the invention of claims 35-38, 52-56, and 62. The original disclosure therefore provides the necessary written description support under 35 U.S.C. § 112, first paragraph, for at least those claims. On this basis, the rejection of claims 35-38, 52-56, and 62 under 35 U.S.C. § 112, first paragraph should be reversed.

B. The obviousness-type double patenting rejection of claims 38, 41, and 56 over the 10/734,599 application is moot because a terminal disclaimer over the '599 application has been filed.

Applicants filed a terminal disclaimer over the 10/734,599 application on or about April 7, 2008. The terminal disclaimer was received and entered by the USPTO as reflected in its Public Patent Application Information Retrieval (Public PAIR) database, rendering the obviousness-type double patenting rejection of claims 38, 41, and 56 over the 10/734,599 application moot. The rejection should be reversed.

C. The obviousness-type double patenting rejection of claims 38, 41, and 56 over the 10/733,869 application is most because a terminal disclaimer over the '869 application has been filed.

Applicants filed a terminal disclaimer over the 10/733,869 application on or about April 7, 2008. The terminal disclaimer was received and entered by the USPTO as reflected in its Public Patent Application Information Retrieval (Public PAIR) database, rendering the

obviousness-type double patenting rejection of claims 38, 41, and 56 over the 10/733,869 application moot. The rejection should be reversed.

## VIII. CONCLUSION

In view of the foregoing arguments, Appellant respectfully submits that the claimed invention is in full compliance with 35 U.S.C. § 112, first paragraph, and the rejections of claims 1-23, 35-48, 50-60, 62, and 63 should be reversed. Appellant also submits that the obviousness-type double patenting rejections of claims 38, 41, and 56 are moot and should be reversed. Appellant respectfully requests reversal of the rejections as applied to the appealed claims and allowance of the entire application.

Authorization to charge the undersigned's deposit account is provided on the cover page of this brief.

Respectfully submitted,

Hollingsworth & Funk, LLC 8009 34<sup>th</sup> Ave South, Suite 125 Minneapolis, MN 55425 952.854.2700

Name: Stephen C. Jense

Reg. No. 35,207

#### **CLAIMS APPENDIX**

1. A method of determining a cardiac response to a pacing pulse, comprising: providing a plurality of electrodes electrically coupled to a heart; delivering the pacing pulse to the heart using a first electrode combination; sensing a single cardiac signal for cardiac response classification following the pacing pulse using a second electrode combination; and classifying the cardiac response to the pacing pulse as one of a captured response, a non-captured response, and a fusion/pseudofusion beat using only the single cardiac signal.

2. The method of claim 1, further comprising:

detecting noise on the cardiac signal; and canceling the classification of the cardiac response based on the detection of noise.

3. The method of claim 1, wherein:

sensing the cardiac signal comprises detecting a characteristic of the cardiac signal; and

classifying the cardiac response comprises:

comparing the detected characteristic to a reference; and classifying the cardiac response based on the comparison.

4. The method of claim 3, wherein:

detecting the characteristic of the cardiac signal comprises detecting an amplitude of the cardiac signal; and

comparing the detected characteristic to a reference comprises comparing the detected amplitude to an amplitude reference.

5. The method of claim 3, wherein:

detecting the characteristic comprises detecting a slope of the cardiac signal; and

comparing the detected characteristic to a reference comprises comparing the detected slope to a slope reference.

#### 6. The method of claim 3, wherein:

detecting the characteristic of the cardiac signal comprises detecting a curvature of the cardiac signal; and

comparing the detected characteristic to a reference comprises comparing the detected curvature to a curvature reference.

### 7. The method of claim 3, wherein:

detecting the characteristic of the cardiac signal comprises detecting a peak width of the cardiac signal; and

comparing the detected characteristic to a reference comprises comparing the detected peak width to a peak width reference.

#### 8. The method of claim 3, wherein:

detecting the characteristic of the cardiac signal comprises detecting one or more feature points of the cardiac signal; and

comparing the detected characteristic to a reference comprises:

providing a template; and

comparing the detected feature points to the template.

#### 9. The method of claim 1, wherein:

delivering the pacing pulse to the heart using a first electrode combination comprises delivering the pacing pulse to using a near-field vector; and sensing the cardiac signal following the pacing pulse using a second electrode combination comprises sensing the cardiac signal using a far-field vector.

#### 10. The method of claim 1, wherein:

delivering the pacing pulse to the heart using a first electrode combination comprises delivering the pacing pulse using a rate channel vector; and

sensing the cardiac signal following the pacing pulse using a second electrode combination comprises sensing the cardiac signal using a shock channel vector.

#### 11. The method of claim 1, wherein:

delivering the pacing pulse to the heart comprises delivering the pacing pulse to a ventricle using the first electrode combination; and

sensing the cardiac signal comprises sensing the cardiac signal using the second electrode combination.

#### 12. The method of claim 1, wherein:

delivering the pacing pulse to the heart comprises delivering the pacing pulse to one ventricle using the first electrode combination; and

sensing the cardiac signal following the pacing pulse comprises sensing the cardiac signal using at least one electrode disposed in the other ventricle.

#### 13. The method of claim 1, wherein:

delivering the pacing pulse to the heart comprises delivering the pacing pulse to an atrium using the first electrode combination; and

sensing the cardiac signal following the pacing pulse comprises sensing a cardiac signal using the second electrode combination.

#### 14. The method of claim 1, wherein:

delivering the pacing pulse to the heart comprises delivering the pacing pulse to one atrium using the first electrode combination; and

sensing the cardiac signal following the pacing pulse comprises sensing a cardiac signal using at least one electrode disposed in the other atrium.

15. A method of determining a cardiac response to a pacing pulse, comprising:

providing a plurality of electrodes electrically coupled to a heart;

delivering the pacing pulse to the heart using a first electrode combination;

sensing a single cardiac signal for cardiac response classification following the pacing pulse using a second electrode combination; and classifying the cardiac response to the pacing pulse as one of at least three cardiac response types using only the single cardiac signal.

- 16. The method of claim 15, further comprising: detecting noise on the cardiac signal; and canceling the classification of the cardiac response based on the detection of noise.
- 17. The method of claim 15, wherein classifying the cardiac response as one of at least three cardiac response types comprises classifying the cardiac response type as a captured response.
- 18. The method of claim 15, wherein classifying the cardiac response as one of at least three cardiac response types comprises classifying the cardiac response type as a non-captured response.
- 19. The method of claim 15, wherein classifying the cardiac response as one of at least three cardiac response types comprises classifying the cardiac response type as a fusion/pseudofusion beat.
- 20. The method of claim 15, wherein classifying the cardiac response as one of at least three cardiac response types comprises classifying the cardiac response type as a near non-captured response.
- 21. The method of claim 15, wherein classifying the cardiac response as one of at least three cardiac response types comprises classifying the cardiac response type as a non-captured response added to an intrinsic beat.
- 22. The method of claim 15, wherein:

sensing the cardiac signal comprises detecting a characteristic of the cardiac signal; and

classifying the cardiac response comprises:

comparing the detected characteristic to a reference; and classifying the cardiac response based on the comparison.

#### 23. The method of claim 15, wherein:

delivering the pacing pulse to the heart using a first electrode combination comprises delivering the pacing pulse to a combination of electrodes associated with a nearfield vector; and

sensing the cardiac signal following the pacing pulse using a second electrode combination comprises sensing the cardiac signal using a far-field vector.

## 35. A method of detecting a fusion/pseudofusion beat, comprising:

providing a plurality of electrodes electrically coupled to a heart;

delivering a pacing pulse to the heart using a first electrode combination;

sensing a single cardiac signal for cardiac response classification following the pacing

pulse using a second electrode combination; and

detecting the fusion/pseudofusion beat using only the single cardiac signal.

#### 36. The method of claim 35, wherein:

sensing the cardiac signal comprises detecting a characteristic of the cardiac signal; and

detecting the fusion/pseudofusion beat comprises:

comparing the detected characteristic to a reference; and detecting the fusion/pseudofusion beat based on the comparison.

#### 37. The method of claim 35, wherein:

delivering the pacing pulse to the heart using a first electrode combination comprises delivering the pacing pulse to using a near-field vector; and

- sensing the cardiac signal following the pacing pulse using a second electrode combination comprises sensing the cardiac signal using a far-field vector.
- 38. The method of claim 35, wherein detecting the fusion/pseudofusion beat comprises:

  defining a plurality of classification windows relative to and subsequent to the pacing pulse;
  - detecting a characteristic of the cardiac signal within a particular classification window; and
  - detecting the fusion/pseudofusion beat based on the detected characteristic and the particular classification window.
- 39. A medical device, comprising:
  - a plurality of electrodes electrically coupled to a heart;
  - a pulse delivery circuit configured to deliver a pacing pulse to a heart using a first electrode combination;
  - a sensing circuit configured to sense a single cardiac signal for cardiac response classification following the pacing pulse using a second electrode combination; and
  - a control circuit, the control circuit coupled to the sensing circuit and configured to classify a cardiac response to the pacing pulse as one of at least three cardiac response types using only the sensed cardiac signal.
- 40. The device of claim 39, wherein the control circuit is further configured to detect the cardiac signal as a noisy signal and to cancel classification of the cardiac response based on the detection of noise.
- 41. The device of claim 39, wherein the control system is configured to define a plurality of classification windows relative to and subsequent to the pacing pulse, detect a characteristic of the cardiac signal within a particular classification window, and classify the cardiac response based on the detected characteristic and the particular classification window.

### 42. The device of claim 39, wherein:

the pulse delivery circuit is configured to deliver the pacing pulse using a near field electrode combination; and

the sensing circuit is configured to sense the cardiac signal using a far field electrode combination.

### 43. The device of claim 39, wherein:

the pulse delivery circuit is configured to delivery the pacing pulse using a rate channel electrode combination; and

the sensing circuit is configured to sense the cardiac signal using a shock channel electrode combination.

### 44. The device of claim 39, wherein:

the a plurality of electrodes includes a right ventricular pacing electrode, a right ventricular coil electrode, and a can electrode;

the pulse delivery circuit is configured to deliver the pacing pulse to the right ventricle using the right ventricular pacing electrode; and

the sensing circuit is configured to sense the cardiac signal using the right ventricular coil electrode and the can electrode.

#### 45. The device of claim 39, wherein:

the plurality of electrodes includes a right chamber pacing electrode and a left chamber sensing electrode;

the pulse delivery circuit is configured to deliver the pacing pulse to a right chamber using the right chamber pacing electrode; and

the sensing circuit is configured to sense the cardiac signal of the right chamber using the left chamber sensing electrode.

### 46. The device of claim 39, wherein:

the plurality of electrodes includes a left chamber pacing electrode and a right chamber sensing electrode; the pulse delivery circuit is configured to deliver the pacing pulse to a left chamber using the left chamber pacing electrode; and

the sensing circuit is configured to sense the cardiac signal of the left chamber using the right chamber sensing electrode.

#### 47. The device of claim 39, wherein:

the plurality of electrodes includes a left ventricular pacing electrode and first and second right ventricular electrodes;

the pulse delivery circuit is configured to deliver the pacing pulse to a left ventricle using the left ventricular pacing electrode; and

the sensing circuit is configured to sense the cardiac signal of the left ventricle using the first and second right ventricular electrodes.

#### 48. The device of claim 39, wherein:

the plurality of electrodes includes first and second right atrial electrodes;

the pulse delivery circuit is configured to deliver the pacing pulse to the right atrium using the first right atrial electrode; and

the sensing circuit is configured to sense the cardiac signal using the second right atrial electrode.

- 50. The device of claim 39, wherein the pulse delivery circuit further comprises a coupling capacitor through which the pacing pulse is delivered.
- 51. The device of claim 50, wherein the coupling capacitor has a value in a range of about 2 microfarads to about 22 microfarads.

## 52. A medical device, comprising:

a plurality of electrodes electrically coupled to a heart;

a pulse delivery circuit and configured to deliver a pacing pulse to a heart using a first electrode combination;

- a sensing circuit and configured to sense a single cardiac signal for cardiac response classification following the pacing pulse using a second electrode combination; and
- a control circuit, the control circuit coupled to the sensing circuit and configured to detect a fusion/pseudofusion beat using only the sensed cardiac signal.
- 53. The device of claim 52, wherein the control circuit is further configured to detect the cardiac signal as a noisy signal and to cancel detection of the fusion/pseudofusion beat based on the detection of noise.

#### 54. The device of claim 52, wherein:

the pulse delivery circuit is configured to deliver the pacing pulse using a rate channel vector; and

the sensing circuit is configured to sense the cardiac signal following the pacing pulse using a shock channel vector.

#### 55. The device of claim 52, wherein:

the pulse delivery circuit is configured to deliver the pacing pulse using an electrode combination associated with a near-field vector; and

the sensing circuit is configured to sense the cardiac signal following the pacing pulse using a far-field vector.

- 56. The device of claim 52, wherein the control system is configured to define a plurality of classification windows relative to and subsequent to the pacing pulse, detect a characteristic of the cardiac signal within a particular classification window, and detect the fusion/pseudo-fusion beat based on the detected characteristic and the particular classification window.
- 57. A medical device for classifying a cardiac response, comprising:

  means for providing a plurality of electrodes electrically coupled to a heart;

  means for delivering the pacing pulse to the heart using a first electrode combination;

  means for sensing a single cardiac signal for cardiac response classification following

  the pacing pulse using a second electrode combination; and

means for classifying the cardiac response to the pacing pulse as one of a captured response, a non-captured response, and a fusion/pseudofusion beat using only the single cardiac signal.

58. The device of claim 57, further comprising:

means for detecting noise on the cardiac signal; and
means for canceling the classification of the cardiac response based on the detection
of noise.

- 59. A medical device for determining a cardiac response to a pacing pulse, comprising:

  means for providing a plurality of electrodes electrically coupled to a heart;

  means for delivering the pacing pulse to the heart using a first electrode combination;

  means for sensing a single cardiac signal for cardiac response classification following

  the pacing pulse using a second electrode combination; and

  means for classifying the cardiac response as one of at least three cardiac response

  types using only the single cardiac signal.
- 60. The device of claim 59, further comprising:

means for detecting noise; and

means for canceling the classification of the cardiac response based on the detection of noise.

- 62. A system for detecting a fusion/pseudofusion beat, comprising:
  - means for providing a plurality of electrodes electrically coupled to a heart;
    means for delivering a pacing pulse to the heart using a first electrode combination;
    means for sensing a single cardiac signal for cardiac pacing response classification
    following the pacing pulse using a second electrode combination; and
    means for detecting the fusion/pseudofusion beat using only the single cardiac signal.
- 63. The device of claim 39, wherein:

the a plurality of electrodes includes a right ventricular pacing electrode, a right ventricular coil electrode, a superior vena cava electrode, and a can electrode; the pulse delivery circuit is configured to deliver the pacing pulse to the right ventricle using the right ventricular pacing electrode; and the sensing circuit is configured to sense the cardiac signal using the right ventricular coil electrode and the superior vena cava electrode tied to the can electrode.

# **EVIDENCE APPENDIX**

None.

# RELATED PROCEEDINGS APPENDIX

None.